



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

October 13, 1999

Jonathan W. Emord, Esq.
Emord & Associates, P.C.
1050 Seventeenth Street, NW
Suite 600
Washington, DC 20036

RE: Health Claim Petition: "Petition for Health Claim: Vitamin E Dietary Supplements and Heart Disease"

Dear Mr. Emord:

This is in reference to the health claim petition that you submitted on behalf of Julian M. Whitaker, MD; Durk Pearson and Sandy Shaw; American Preventive Medical Association; and Pure Encapsulations, Inc., on July 6, 1999 to the Food and Drug Administration. In accordance with section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act, we will be filing this petition. At the time of filing, health claim petitions are placed in a public docket and become available for public review. However, the filing of a health claim petition does not indicate that the agency has completed its review nor determined whether all preliminary requirements for the petition have been satisfied. FDA is required to make a decision about whether to issue a proposed regulation within 90 days of the filing date and, therefore, will be conducting further review of the information in your petition.

Please feel free to contact me at the above address or call me at 202-205-4500 if you have any questions.

Sincerely,

Susan M. Pilch, Ph.D.
Team Leader- Nutrition, Health Claims, and Dietary Supplements
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition

cc:
GCF-1 (Overholser, Liberman)
HFS-450 (Yetley)
HFS-45 1 (Lewis)

99P-4375

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